

### **REMARKS**

Claims 1, 2, 4-13, 21-25, 27-46 and 55-57 are pending in this application. Claims 3 and 26 previously were cancelled. Claims 14-20 and 47-54 previously were withdrawn. Claims 1, 2, 5, 8, 10, 11, 21, and 55 have been amended to delete "at least" before the lower end of the range for cetylpyridinium chloride ("CPC"). In addition, Claims 1, 8, 21, 22, and 34 have been amended to recite that the maximum amount of CPC is 9.5 ppm, support for which may be found in Table 1 on page 25 of the specification.

Applicants retain the right to present claims 14-20 and 47-54 in a divisional application. The amendments herein have been made to expedite prosecution only and should not be construed as a waiver.

#### **35 U.S.C. §112 Rejections**

Claims 1, 2, 5, 8, 10, 11, 21, and 55 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office objects to the use of the phrase "at least about" as unclear. The Applicants respectfully disagree. The phrase "at least about" is ubiquitous in patent claims disclosing ranges and its meaning is clear. However, to expedite prosecution, the Applicants have amended the claims to delete "at least." Accordingly, this rejection is moot and should be withdrawn.

#### **35 U.S.C. §103 Rejections**

Claims 1-2, 4-13, and 22-33 are rejected under 35 USC 103(a) as obvious over US 6,482,799 ("Tuse") in view of US 3,882,036 ("Krezanoski"), US 2003/0228393 ("Zhao"), US 2003/0105167 ("Dyken"), and US 2004/0120916 ("Huth"). The Applicants respectfully disagree. However, in order to expedite prosecution only, Claims 1, 8, 21, and 22 have been amended to recite that the maximum amount of CPC is about 9.5

ppm. Since none of the references disclose about 0.1 to about 9.5 ppm CPC, there can be no *prima facie* obviousness.

Every limitation of the present claims must be found in the prior art. None of the cited references disclose about 0.1 to about 9.5 ppm CPC in accordance with independent claims 1, 8, 21, 22, and 34 or about 0.1 ppm to about 2 ppm CPC in accordance with independent Claim 55. As discussed previously, the antimicrobial activity of CPC is reduced by certain non-ionic surfactants (e.g., Tween 80) that are commonly used in ophthalmic solutions.<sup>1</sup> However, the Applicants surprisingly discovered that a synergy exists between CPC and certain other non-ionic surfactants (i.e., poly(oxypropylene)-poly(oxyethylene) block copolymers).<sup>2</sup> As such, a skilled artisan would not have been led to utilize a combination of CPC and poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants based on the cited references.<sup>3</sup>

In addition, after discovering the synergistic link between CPC and poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants, the skilled artisan must then use between about 0.1 and about 9.5 ppm CPC, which none of the cited references disclose. The only reference that discloses any relevant CPC concentrations is Krezanoski.<sup>4</sup> Krezanoski states unequivocally that in "[i]n order to maintain sterility of the product during use, the preferred quaternary or organic mercurial germicide should be present in an amount of about 0.001 to 0.03% of the overall solution, and preferably in concentrations of from 0.004 to 0.02% The optimum concentration is about 0.01%."<sup>5</sup> As the Office recognized, the broadest range disclosed by Krezanoski is 10 ppm to 300 ppm CPC.<sup>6</sup> If Krezanoski motivates the skilled artisan to experiment with CPC amounts at all, that encouragement would lead the skilled

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<sup>1</sup> Specification, p. 26, Table 2 and lines 1-3.

<sup>2</sup> Specification, pp. 26-27, compare results in Tables 2 & 3.

<sup>3</sup> 11/21/2007 Amendment and Remarks, pp. 16-18.

<sup>4</sup> Krezanoski, col. 6, lines 16-22.

<sup>5</sup> Krezanoski, col. 6, lines 16-22.

<sup>6</sup> 02/08/2008 Office Action, pp. 6, 9, 12, and 15.

artisan toward the Krezanoski's "optimum concentration" of 100 ppm CPC, not the presently-claimed about 0.1 and about 9.5 ppm CPC.

Since the Office has failed to show why a skilled artisan would combine CPC with poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants and since none of the cited references disclose the use of about 0.1 to about 9.5 ppm of CPC, the Office has failed to establish a prima facie case of obviousness. Accordingly, the Applicants respectfully request withdrawal of this rejection.

Claim 21 is rejected under 35 USC 103(a) as obvious over Tuse in view of Krezanoski, Zhao, and Huth. As discussed above, none of the cited references disclose the combination of CPC and poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants or the use of about 0.1 to about 9.5 ppm of CPC, which Claim 21 requires. Accordingly, the Applicants respectfully request withdrawal of this rejection.

Claims 34-46 are rejected under 35 USC 103(a) as obvious over Tuse in view of Krezanoski, Zhao, Dykens, and Huth. As discussed above, none of the cited references disclose the combination of CPC and poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants or the use of about 0.1 to about 9.5 ppm of CPC, which independent Claim 34 and dependent Claims 35-46 all require. Accordingly, the Applicants respectfully request withdrawal of this rejection.

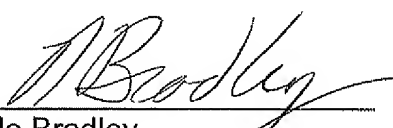
Claims 55-57 are rejected under 35 USC 103(a) as obvious over Tuse in view of Krezanoski. As discussed above, none of the cited references disclose the combination of CPC and poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants or the use of about 0.1 to about 2 ppm of CPC, which independent Claim 55 and dependent Claims 56-57 all require. Accordingly, the Applicants respectfully request withdrawal of this rejection.

**CONCLUSION**

The Applicants respectfully submit that the pending claims are in condition for allowance and request that timely Notice of Allowance be issued. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment, or credit any overpayment, to Deposit Account No. 502317.

Respectfully submitted,

Dated: 4/29/08

  
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